

## JAN 10 2003 IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Chang-Zheng Chen and Harvey F. Lodish  
 Application No.: 10/077,178 Group Art Unit: 1645  
 Filed: February 15, 2002 Examiner: Not Yet Assigned  
 Confirmation No.: 9519  
 Title: Stem Cell Self-Renewal and Lineage Commitment

# 5 / K. T. 3/13  
 TECH CENTER 1600 1/2000

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**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, P.O. Box 2327, Arlington, VA 22202

on 1-16-03 Jane Morgan  
 Date Signature

JANE MORGAN  
 Typed or printed name of person signing certificate

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
 P.O. Box 2327  
 Arlington, VA 22202

Sir:

This Information Disclosure Statement is submitted:

under 37 CFR 1.129(a), or  
 (First/Second submission after Final Rejection)

under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

under 37 CFR 1.97(c) together with either:

a Statement under 37 CFR 1.97(e), as checked below, or  
 a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

under 37 CFR 1.97(d) together with:

a Statement under 37 CFR 1.97(e), as checked below, and  
 a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.  
 (Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Enclosed herewith is form PTO-1449:

- Copies of cited references AL, AM, AR-AZ, AR2-AZ2, AR3-AZ3, AR4-AZ4 and AR5-AZ5 are enclosed.
- Copies of cited references are enclosed except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
- The listed references (AL and AR-AT) were cited in the enclosed International Search Report in a counterpart foreign application.
- The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:
  - the explanation provided on the attached sheet.
  - the explanation provided in the Specification.
  - submission of the enclosed International Search Report.
  - submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
  - the enclosed English language abstract.

[ ] Applicant requests that the following non-published pending applications be considered:

Examiner's  
Initials

\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

Examiner \_\_\_\_\_

Date \_\_\_\_\_

[ ] A copy of each above-cited application, including the current claims, is enclosed.

[ ] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

[ ] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

[ ] Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.

[X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

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Dated:

January 6, 2003

PTO-1449 REPRODUCED

ATTORNEY DOCKET NO.  
0399.2027-001APPLICATION NO.  
10/077,178

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INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION  
JAN 10 2003 January 3, 2003  
(Use several sheets if necessary)

APPLICANT  
Chang-Zheng Chen and Harvey F. LodishFILING DATE  
February 15, 2002CONFIRMATION NO.  
9519GROUP  
1645

## U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	DOCUMENT NUMBER	ISSUE DATE / PUBLICATION DATE	NAME
AA			

## FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES	NO
AL	WO 99/53022	21-OCT-1999	PCT				
AM	WO 99/53022 A3	21-OCT-1999	PCT				

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AR	Elefanty, A.G., et al., "Characterization of Hematopoietic Progenitor Cells That Express The Transcription Factor SCL, Using a lacZ 'knock-in' Strategy," <i>Proc. Natl. Acad. Sci. USA</i> 95(20):11897-11902 (1998).
AS	Jordan, C.T., et al., "Recent Progress in Identifying Genes Regulating Hematopoietic Stem Cell Function and Fate," <i>Curr. Opin. Cell Biol.</i> 10(6):716-720 (1998).
AT	Wang, S., et al., "Isolation of Neuronal Precursors By Sorting Embryonic Forebrain Transfected With GFP Regulated By The Tal Tubulin Promoter," <i>Nature Biotechnol.</i> 16(2):196-201 (1998).
AU	Morrison, S.J., et al., "Regulatory Mechanisms in Stem Cell Biology," <i>Cell</i> , 88:287-298 (1997).
AV	Weissman, I.L., "Stem Cells: Units of Development, Units of Regeneration, and Units in Evolution," <i>Cell</i> , 100:157-168 (2000).
AW	Kondo, M., et al., "Identification of Clonogenic Common Lymphoid Progenitors in Mouse Bone Marrow," <i>Cell</i> , 91:661-672 (1997).
AX	Georgopoulos, K., et al., "The Ikaros Gene is Required for the Development of All Lymphoid Lineages," <i>Cell</i> , 79:143-156 (1994).
AY	Winandy, S., et al., "A Dominant Mutation in the Ikaros Gene Leads to Rapid Development of Leukemia and Lymphoma," <i>Cell</i> , 83:289-299 (1995).
AZ	Akashi, K., et al., "A Clonogenic Common Myeloid Progenitor That Gives Rise to All Myeloid Lineages," <i>Nature</i> , 404:193-197 (2000).
AR2	Shivdasani, R.A., et al., "Absence of Blood Formation in Mice Lacking the T-cell Leukaemia Oncoprotein tal-1/SCL," <i>Nature</i> , 373:432-434 (1995).
AS2	Weissman, I.L., "Translating Stem and Progenitor Cell Biology to the Clinic: Barriers and Opportunities," <i>Science</i> , 287:1442-1446 (2000).

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TECH CENTER 1600/290

PTO-1449 REPRODUCED

ATTORNEY DOCKET NO.  
0399.2027-001APPLICATION NO.  
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## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AT2	Klug, C.A., et al., "Hematopoietic Stem Cells and Lymphoid Progenitors Express Different Ikaros Isoforms, and Ikaros is Localized to Heterochromatin in Immature Lymphocytes," <i>Proc. Natl. Acad. Sci. USA</i> , 95:657-662 (1998).
AU2	Skarnes, W.C., et al., "Capturing Genes Encoding Membrane and Secreted Proteins Important for Mouse Development," <i>Proc. Natl. Acad. Sci. USA</i> 92:6592-6596 (1995).
AV2	Szilvassy, S.J., et al., "Quantitative Assay for Totipotent Reconstituting Hematopoietic Stem Cells by a Competitive Repopulation Strategy," <i>Proc. Natl. Acad. Sci. USA</i> , 87:8736-8740 (1990).
AW2	Moore, K.A., et al., "In Vitro Maintenance of Highly Purified, Transplantable Hematopoietic Stem Cells," <i>Blood</i> , 89(12):4337-4347 (1997).
AX2	Audet, J., et al., "Advances in Hematopoietic Stem Cell Culture," <i>Curr. Opin. Biotechnol.</i> , 9(2):146-151 (1998).
AY2	Lemischka, I., et al., "Searching for Stem Cell Regulatory Molecules: Some General Thoughts and Possible Approaches," <i>Ann. N.Y. Acad. Sci.</i> , 872:274-288 (1999).
AZ2	Jordan, C.T., et al., "Long-term Repopulating Abilities of Enriched Fetal Liver Stem Cells Measured by Competitive Repopulation," <i>Exp. Hematol.</i> , 23:1011-1015 (1995).
AR3	Ploemacher, R.E., et al., "An In Vitro Limiting-Dilution Assay of Long-Term Repopulating Hematopoietic Stem Cells in the Mouse," <i>Blood</i> , 74(8):2755-2763 (1989).
AS3	Eaves, C.J., et al., "Molecular Analysis of Primitive Hematopoietic Cell Proliferation Control Mechanisms," <i>Ann. N.Y. Acad. Sci.</i> , 628:298-306 (1991).
AT3	Yang, X.W., et al., "BAC-mediated Gene-dosage Analysis Reveals a Role for Ziprol (Ru49/Zfp38) in Progenitor Cell Proliferation in Cerebellum and Skin," <i>Nature Genet.</i> , 22(4):327-335 (1999).

EXAMINER

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PTO-1449 REPRODUCED			ATTORNEY DOCKET NO. 0399.2027-001	APPLICATION NO. 10/077,178			
<b>O I P E</b> <b>INFORMATION DISCLOSURE CITATION</b> <b>IN AN APPLICATION</b> <b>JAN 10 2003</b> <b>January 3, 2003</b> <b>(Use several sheets if necessary)</b>			APPLICANT Chang-Zheng Chen and Harvey F. Lodish				
			FILING DATE February 15, 2002	CONFIRMATION NO. 9519	GROUP 1645		
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<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
AU <sup>3</sup>	Metcalf, D., "Stem Cells, Pre-Progenitor Cells and Lineage-Committed Cells: Are Our Dogmas Correct?," <i>Ann. N.Y. Acad. Sci.</i> , 872:289-304 (1999).						
AV <sup>3</sup>	Begley, C.G., et al., "The SCL Gene: From Case Report to Critical Hematopoietic Regulator," <i>Blood</i> , 93(9):2760-70 (1999).						
AW <sup>3</sup>	Georgopoulos, K., "Transcription Factors Required for Lymphoid Lineage Commitment," <i>Curr. Opin. Immunol.</i> , 9:222-227 (1997).						
AX <sup>3</sup>	Elefanti, A.G., et al., "SCL Expression in the Mouse Embryo Detected With a Targeted lacZ Reporter Gene Demonstrates Its Localization to Hematopoietic, Vascular, and Neural Tissues," <i>Blood</i> , 94(11):3754-3763 (1999).						
AY <sup>3</sup>	Porcher, C., et al., "Specification of Hematopoietic and Vascular Development by the bHLH Transcription Factor SCL Without Direct DNA Binding," <i>Development</i> , 126:4603-4615 (1999).						
AZ <sup>3</sup>	Green, A.R., et al., "Antisense SCL Suppresses Self-renewal and Enhances Spontaneous Erythroid Differentiation of the Human Leukaemic Cell Line K562," <i>EMBO J.</i> , 10(13):4153-4158 (1991).						
AR <sup>4</sup>	Green, A.R., et al., "Erythroid Expression of the 'Helix-Loop-Helix' Gene, SCL," <i>Oncogene</i> , 6:475-479 (1991).						
AS <sup>4</sup>	Molnár, A., et al., "The Ikaros Gene Encodes a Family of Functionally Diverse Zinc Finger DNA-Binding Proteins," <i>Mol. Cell Biol.</i> , 14(12):8292-8303 (1994).						
AT <sup>4</sup>	Nichogiannopoulou, A., et al., "Defects in Hemopoietic Stem Cell Activity in Ikaros Mutant Mice," <i>J. Exp. Med.</i> , 190(9):1201-1213 (1999).						
EXAMINER			DATE CONSIDERED			<b>RECEIVED</b> <b>JAN 13 2003</b> <b>TECH CENTER 160/2900</b>	

<p>PTO-1449 REPRODUCED</p> <p>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</p> <p>January 3, 2003</p> <p>(Use several sheets if necessary)</p>			ATTORNEY DOCKET NO. 0399.2027-001	APPLICATION NO. 10/077,178			
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
AU <sup>4</sup>	Dillon, N., et al., "Transcriptional Regulation of Multigene Loci: Multilevel Control," <i>Trends Genet.</i> , 9(4):134-137 (1993).						
AV <sup>4</sup>	Wilson, C., et al., "Position Effects on Eukaryotic Gene Expression," <i>Ann. Rev. Cell Biol.</i> , 6:679-714 (1990).						
AW <sup>4</sup>	Ploemacher, R.E., et al., "Characteristics of the CFU-s Population in Mice Carrying the S <sup>1</sup> Allele," <i>Cell Tissue Kinet.</i> , 17(1):1-12 (1984).						
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AY <sup>4</sup>	Lemieux, M.E., et al., "Characterization and Purification of a Primitive Hematopoietic Cell Type in Adult Mouse Marrow Capable of Lymphomyeloid Differentiation in Long-Term Marrow 'Switch' Cultures," <i>Blood</i> , 86(4):1339-1347 (1995).						
AZ <sup>4</sup>	Szilvassy, S.J., et al., "Isolation in a Single Step of a Highly Enriched Murine Hematopoietic Stem Cell Population With Competitive Long-Term Repopulating Ability," <i>Blood</i> , 74(3):930-939 (1989).						
AR <sup>5</sup>	Goodell, M.A., et al., "Isolation and Functional Properties of Murine Hematopoietic Stem Cells that are Replicating In Vivo," <i>J. Exp. Med.</i> , 183(4):1797-1806 (1996).						
AS <sup>5</sup>	Sánchez, M.-J., et al., "An SCL 3' Enhancer Targets Developing Endothelium Together With Embryonic and Adult Haematopoietic Progenitors," <i>Development</i> , 126:3891-3904 (1999).						
AT <sup>5</sup>	Brennan, J., et al., "Gene Trapping in Mouse Embryonic Stem Cells," <i>Methods Mol. Biol.</i> , 97:123-138 (1999).						
EXAMINER			DATE CONSIDERED			<p>RECEIVED JAN 13 2003 TECH CENTER 1600/2900</p>	

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AUS	Liu, X., et al., "Generation of Mammalian Cells Stably Expressing Multiple Genes at Predetermined Levels," <i>Anal. Biochem.</i> , 280(1):20-28 (2000).						
AV5	Hua, X., et al., "Synergistic Cooperation of TFE3 and Smad Proteins in TGF- $\beta$ -induced Transcription of the Plasminogen Activator Inhibitor-1 Gene," <i>Genes Dev.</i> , 12(19):3084-3095 (1998).						
AW5	Ema, H., et al., "Expansion of Hematopoietic Stem Cells in the Developing Liver of a Mouse Embryo," <i>Blood</i> , 95(7):2284-2288 (2000).						
AX5	Naviaux, R.K., et al., "The pCL Vector System: Rapid Production of Helper-Free, High-Titer, Recombinant Retroviruses," <i>J. Virol.</i> , 70(8):5701-5705 (1996).						
AY5	Yang, X.W., et al., "Homologous Recombination Based Modification in <i>Escherichia coli</i> and Germline Transmission in Transgenic Mice of a Bacterial Artificial Chromosome," <i>Nature Biotechnol.</i> , 15:859-865 (1997).						
AZ5	Visvader, J., et al., "Helix-Loop-Helix Genes Translocated in Lymphoid Leukemia," <i>TIBS</i> , 16(9):330-333, (1991).						
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